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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,499	01/12/2004	Bernhard Freund	0652.1760003/DKSC/AFK	8272

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

TREYGER, ILYA Y

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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06/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/754,499	Applicant(s) FREUND ET AL.	
	Examiner ILYA Y. TREYGER	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19,25 and 31-36 is/are allowed.
- 6) ☒ Claim(s) 1,5-12,20-24,28 and 29 is/are rejected.
- 7) ☒ Claim(s) 4,13-18,26 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/08/2010;04/13/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/08/2010 has been entered.
2. Claims 1, 4, 13, 19, 20, 25 and 26 are amended.
3. Claims 2, 3 and 27 are canceled.
4. Claims 29-36 are new
5. Claims 1 and 4-26 and 28-36 are examined on the merits.

Response to Arguments

6. Applicant's arguments filed 07/31/2009 have been fully considered but they are not persuasive:

With respect to amended claims 1 and 20, Applicants argue that the combination of references does not disclose the claimed invention because the references of Osgar and Bodicky does not disclose a container, wherein the flange is a monolithic structure including the pierceable membrane and the guide passage.

However, the newly discovered reference of Weiler teaches a container having pierceable insert (flange) 16 (Fig. 3) comprising an elongated member 18 (Fig. 3) defining a passageway (guide passage) 32 (Fig. 3) sealed by a membrane 24 (Fig. 3) that is integral with the insert member (col. 3, lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Osgar/ Bodicky with the insert member being monolithic structure including the pierceable membrane and the guide passage, as taught by Weiler in order to improve the mechanical reliability of the flange.

7. With respect to claims 4, 13-19, 25, 26 and 30-36, see Allowable Subject Matter below.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The trademark or trade name is used in claim 24 as a limitation to identify or describe a particular material or product, therefore claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982).

The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. See MPEP 2175.05(u)

a. Objections to Specification

The use of the trademark [1] has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Proper usage of trademarks requires that they be capitalized at all times. See MPEP § 608.01(v).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 5 and 29 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Osgar et al. (US 5,102,010) in view of Bodicky et al. (US 4,976,707), and further in view of Weiler et al. (US 4,519,513).

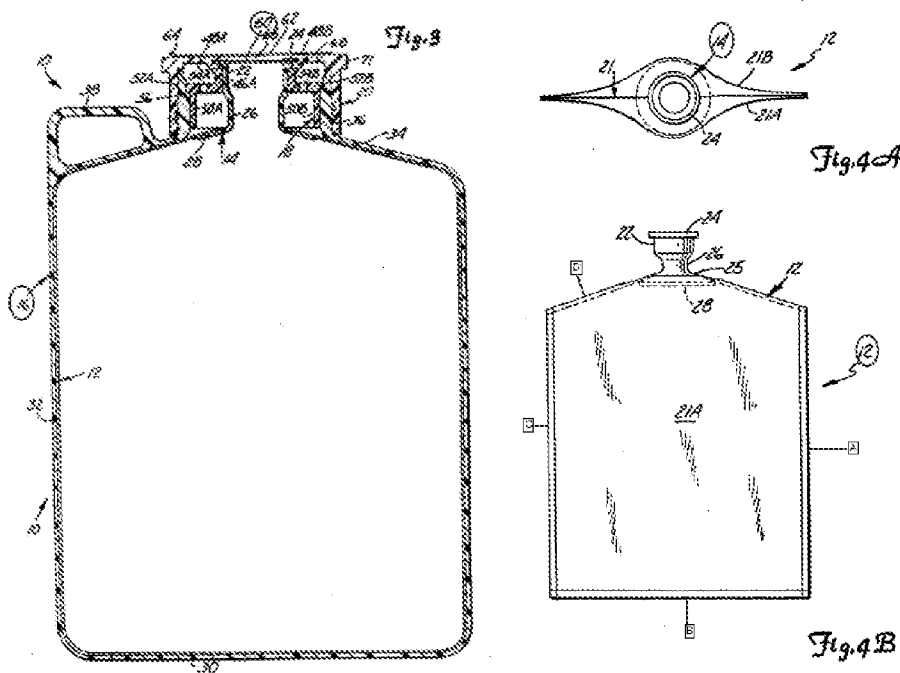
14. In Re claim 1, Osgar discloses a gas-tight and liquid-tight (Col. 4, ln. 21) container for a medical liquid including pharmaceuticals that includes

a collapsible (Col. 4, ln. 37-39) foil bag 12 (Col. 3, ln. 24) with a welded seam A,B,B,D;

a flange 14 with a passage through the flange and a sealing location within the flange.

The flange is sealed to the foil bag (Col. Abstract, ln. 5-6; Col. 3, ln. 36-38).

A pierceable membrane 60, which must be pierced (Col. 4, ln. 14-16) upon connection of the discharge member (See Figs. 3, 4A, and 4B).



Osgar does not expressly disclose the specific parameter of the pressure the foil bag is collapsible at.

The pressure collapsing the bag depends of the resistance of the walls of the bag (material the bag is produced from and thickness of the walls) and therefore is the matter of optimization.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)), therefore it would have been obvious to find the optimum value of the pressure in order to provide even discharge of the bag.

Osgar does not expressly disclose the bag having at least one welded seam of a substantially T-shaped or substantially V-shaped configuration.

Bodicky teaches a fluid collection bag (Abstract, line 1) having a welded seam of a V-shaped configuration (Col. 4, line 58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the welded seam of a collapsible bag of Osgar of the V-shaped configuration, as taught by Bodicky in order to simplify the production process utilizing the collapsible bag of the conventionally known configuration.

In addition, omission of an element and its function is obvious if the function of the element is not desired *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). In the instant case the bag of Bodicky comprises the outlet port 73 that affects the closure of the end of the bag, and therefore may be removed along with its function.

Osgar in view of Bodicky do not expressly disclose a container, wherein the flange is a monolithic structure including the pierceable membrane and the guide passage.

Weiler teaches a container having pierceable insert (flange) 16 (Fig. 3) comprising an elongated member 18 (Fig. 3) defining a passageway (guide passage) 32 (Fig. 3) sealed by a membrane 24 (Fig. 3) that is integral with the insert member (col. 3, lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Osgar/ Bodicky with the insert member being monolithic structure including the pierceable membrane and the guide passage, as taught by Weiler in order to improve the mechanical reliability of the flange.

15. In Re claim 5, Osgar discloses the foil bag made from a layered material (Col. 3, ln. 24-26).

16. In Re claim 29, Osgar discloses a bag having a T-shaped welded seam B (Fig. 4B).

17. Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osgar et al. (US 5,102,010) in view of Bodicky et al. (US 4,976,707) and Weiler et al. (US 4,519,513), and further in view of Carlisle (US 3,878,977).

18. In Re claim 6, Osgar in view of Bodicky and Weiler disclose the claimed invention discussed above, but do not expressly disclose a container wherein a first layer of said composite material includes a metal selected from the group consisting of aluminum, gold, and copper.

Carlisle teaches that it is known to use a container wherein the layer of the composite material includes an aluminum foil (Col. 9, ln. 21).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the foil of Carlisle into the invention of Osgar/ Bodicky/ Weiler to improve thermal insulation of the medicament. Both inventions are drawn to fluid containment are analogous in the art and therefore a combination is proper.

19. In Re claim 7, Osgar discloses the container comprises an inner foil of a plastic material and an outer foil of a metal material (See Col. 3, ln. 24-26).

20. In Re claim 8, Osgar discloses the container comprises two foils of different plastic materials (See Col. 3, ln. 24-26).

21. In Re claim 9, Carlisle inherently discloses that it is known to make a flexible container of two layers wherein the melting temperature of second plastic material is higher than the melting temperature of the inner foil, since different plastics have different melting temperature (See Col. 9, ln. 23-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the flexible container of Osgar/ Bodicky/ Weiler from two different plastics, as taught by Carlisle, because such modification would simplify the production process.

22. In Re claim 10, Carlisle teaches that it is known to use a flexible container wherein the diffusion-tight central layer is made from a plastic material (See Col. 9, ln. 16-38).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

23. In Re claim 11, Carlisle teaches that it is known to make the outer foil of polyethylene terephthalate (See Col. 9, ln. 23).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

24. In Re claim 12, Carlisle teaches that it is known to make the inner foil of the flexible container of a polyethylene copolymer of ethylene-acrylic acid (See Col. 9, ln. 38).

The rationale of obviousness rejection discussed above in claim 6 is incorporated herein in its entirety.

25. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010), and further in view of Weiler et al. (US 4,519,513).

26. In Re claim 20, Schreiber discloses an atomizer (Col. 5, lines 41-45) with a discharge connection for dispensing medicament disposed in the attached vial 12 (Fig. 1) in predetermined doses (Col. 2, ln. 62-63), wherein the atomizer is interpreted as being gas-free, since no propellant gas has been used (Col. 4, lines 46-68; Col. 5, lines 1-12). Schreiber does not expressly disclose a collapsible container as claimed. Osgar teaches that it is known to use a gas-tight and liquid-tight (Col. 4, ln. 21) container for a medical liquid including pharmaceuticals that includes

a collapsible (Col. 4, ln. 37-39) foil bag 12 (Col. 3, ln. 24) with a welded seam A,B,B,D;
a flange 14 with a passage through the flange and a sealing location within the flange.

The flange is sealed to the foil bag (Col. Abstract, ln. 5-6; Col. 3, ln. 36-38).

A pierceable membrane 60, which must be pierced (Col. 4, ln. 14-16) upon connection of the discharge member (See Figs. 3, 4A, and 4B).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vial of Schreiber with the collapsible container, as taught by Osgar, because such modification would decrease the cost of the system.

Schreiber in view of Osgar do not expressly disclose a container, wherein the flange is a monolithic structure including the pierceable membrane and the guide passage.

Weiler teaches a container having pierceable insert (flange) 16 (Fig. 3) comprising an elongated member 18 (Fig. 3) defining a passageway (guide passage) 32 (Fig. 3) sealed by a membrane 24 (Fig. 3) that is integral with the insert member (col. 3, lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Schreiber / Osgar with the insert member being monolithic structure including the pierceable membrane and the guide passage, as taught by Weiler in order to improve the mechanical reliability of the flange.

27. In Re claims 21 and 22, Schreiber/ Osgar/ Weiler disclose the claimed invention discussed above, but do not expressly disclose the specific dosage the medicament is taken in.

The particular dosage of medicament depends of the particular disease, condition of the patient, and patient's age, and therefore is the matter of optimization.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233(MPEP 2144.05 (II-A)).

28.

29. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010) and Weiler et al. (US 4,519,513), as applied to claim 20 above, and further in view of Kief (US 6,303,152).

Schreiber in view of Osgar and Weiler disclose the claimed invention discussed above, but do not expressly disclose the medicament in a solution of ethanol, water, or a mixture thereof.

Kief teaches that it is known to use water (Col. 6, ln. 43-44) as a solvent for inhalable solutions (Col. 3, ln. 36-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Schreiber/ Osgar/ Weiler with the medicament in a solution of water, as taught by Kief, because such modification would simplify the sterilization process of the medicament.

30. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010), and further in view of Weiler et al. (US 4,519,513), as applied to claim 20 above, and further in view of Andersson et al. (US 5,934,273).

Schreiber in view of Osgar and Weiler disclose the claimed invention discussed above, but do not expressly disclose the medicament including at least one active substance selected from the group consisting of one or more of the following: BEROTEC (fenoterol-hydrobromide; 1-(3,5-dihydroxyphenyl)-2-[[1-(4-hydroxybenzyl)-ethyl]-amino]-ethanol-hydrobromide), ALTROVENT (ipratropium bromide), BERODUAL (combination of fenoterol-hydrobromide and ipratropium-bromide), SALBUTAMOL or LBUTEROL, COMBIVENT, OXIVENT (oxitropium bromide), BA 679 (tiotropium bromide), BEA 2108 (di-(2-thienyl)-glycol acid tropenol ester), FLUNISOLID, BUDESONID, BECLOMETHASON.

Andersson teaches that it is known to use SALBUTAMOL and BUDESONID for inhalation purposes (Col. 4, ln. 11, 18)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Schreiber/ Osgar/ Weiler with the SALBUTAMOL and BUDESONID, as taught by Andersson, because such modification would allow the system to be used in cases when claimed medicaments are required.

31. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreiber (US 5,176,654) in view of Osgar et al. (US 5,102,010) and further in view of Weiler et al. (US 4,519,513), as applied to claim 20 above, and further in view of Bodicky et al. (US 4,976,707).

Schreiber in view of Osgar disclose the invention discussed above but do not expressly disclose the bag having at least one welded seam of a substantially T-shaped or substantially V-shaped configuration.

Bodicky teaches a fluid collection bag (Abstract, line 1) having a welded seam of a V-shaped configuration (Col. 4, line 58).

The rationale of obviousness rejection discussed above in claim 1 is incorporated herein in its entirety.

Allowable Subject Matter

32. Claims 19, 25 and 31-36 are allowed.

33. Claims 4, 13-18, 26 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

34. The following is an examiner's statement of reasons for allowance: The closest Prior Art of record US 5,102,010, US 4,976,707, US 4,519,513 and US 5,176,654 fail to teach or suggest the "pierceable membrane disposed at an end of or within the end portion of the guide passage",

the “pierceable membrane arranged between the press fit of the guide passage and an interior chamber of the bag”, and “a press fit within the guide passage”.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Ilya Y Treyger/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761